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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR     | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|--------------------------|---------------------|------------------|
| 10/683,747      | 10/10/2003  | Pieter Jurjen Groenewoud | M009.P005U1         | 2830             |

25854                      7590                      02/21/2007  
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EXAMINER

HUYNH, CARLIC K

ART UNIT                      PAPER NUMBER

1617

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE  | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS                               | 02/21/2007 | PAPER         |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/683,747 | <b>Applicant(s)</b><br>GROENEWOUD ET AL. |  |
|                              | <b>Examiner</b><br>Carlic K. Huynh   | <b>Art Unit</b><br>1617                  |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 01 December 2006.
- 2a)  This action is FINAL.
- 2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 1-22 is/are pending in the application.
  - 4a) Of the above claim(s) 13-22 is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1-12 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on 10 October 2003 is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    - a)  All    b)  Some \*    c)  None of:
      - 1.  Certified copies of the priority documents have been received.
      - 2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
      - 3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date See Continuation Sheet.
- 4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5)  Notice of Informal Patent Application
- 6)  Other: \_\_\_\_\_.

Continuation of Attachment(s) 3. Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :16 January 2004 and 27 September 2006.

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1-22 are pending in the application, with claims 13-22 having been withdrawn from consideration, in response to the restriction requirement submitted on November 3, 2006. Accordingly, claims 1-12 are being examined on the merits herein.

### ***Election/Restrictions***

2. Applicant's election without traverse of the claims of Group I, namely claims 1-12, in the reply filed on December 1, 2006 is acknowledged.

Claims 13-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made without traverse in the reply filed on December 1, 2006.

The election/restriction requirement is deemed proper and is made FINAL.

### ***Information Disclosure Statement***

The Information Disclosure Statement submitted on January 16, 2004 and September 27, 2006 is acknowledged.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 1 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "dry" in claim 1, step (a) and in claim 10, step (a) is a relative term which renders the claim indefinite. The term "dry" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The use of the relative term "dry" renders the mixing of ibuprofen, narcotic analgesic, and at least one excipient indefinite.

The term "substantially dry" in claim 1, step (b) and in claim 10, step (b) is a relative term which renders the claim indefinite. The term "substantially dry" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The use of the relative term "substantially dry" renders the formation of a compact material indefinite.

4. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "dry" in claim 4 is a relative term which renders the claim indefinite. The term "dry" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The use of the relative term "dry" renders the mixing and addition of at least one excipient indefinite.

*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-2 and 4-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Kushla et al. (U.S. Patent No 6,348,216).

Regarding "dry powder phase" in claim 1, step (a) and claim 10, step (a), given their broadest interpretation, the claim read on a powder form of ibuprofen, a narcotic analgesic, and at least one excipient.

Kushla et al. teach a method of granulating ibuprofen and a narcotic analgesic to form granules, blending the granules into a blend, and compressing the blend to form tablets (column 3, lines 35-44).

Kushla et al. also teach various excipients such as croscarmellose sodium, microcrystalline cellulose, and magnesium stearate (column 6, table 1), the incorporation of the excipients in the tablet production process (column 4, lines 50-58, for example), hydrocodone bitartate as the narcotic analgesic (column 2, line 9), and the amount of ibuprofen and hydrocodone bitartate in each tablet (column 4, lines 63-64).

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 102(b).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 3 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kushla et al. (U.S. Patent No 6,348,216) as applied to claims 1-2 and 4-11 above in view of Arnold (U.S. Patent No. 4,587,252).

Kushla et al. teach compressing granules into tablets (column 4, line 59).

Kushla et al. do not teach a caplet dosage form.

Arnold teaches hydrocodone-ibuprofen compositions as tablet or caplet dosage forms (column 2, lines 46-47).

To a person of skill in the art at the time of the invention, it would have been obvious to employ the method of Kushla et al. to make caplets because the caplets of Arnold can be made and according to Arnold, caplets can be made of an ibuprofen-narcotic analgesic pharmaceutical composition.

The motivation to combine the method of Kushla et al. to the caplets of Arnold is that the caplets of Arnold can be made of an ibuprofen-narcotic analgesic pharmaceutical composition.

***Conclusion***

7. No claims are allowed.

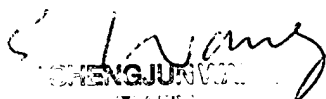
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ckh

  
CHENGJUN WU